IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	Art Unit: 1797
R. Sam NIEDBALA *et al.*	Examiner: Lyle A. ALEXANDER
Application Serial No.: 09/997,023	Confirmation No: 6134
Filed: November 30, 2001	
For: SAMPLE COLLECTOR AND TEST DEVICE	Date: July 22, 2010

U.S. Patent and Trademark Office
Mail Stop **RCE**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

In response to the Office Action mailed November 30, 2009, please amend the above-identified application as indicated below. Applicants respectfully submit this Amendment concurrently with a Request for Continued Examination (RCE) under 37 CFR § 1.114. Applicants respectfully request withdrawal of the Notice of Appeal filed on April 29, 2010.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 13 of this paper.

AMENDMENTS TO THE CLAIMS

Please amend claims 1, 6, 7, 12-14, 18, 20, 21, 23, 25, 46-49, 51, 73, 74, and 77 as shown in the listing of claims below. Please cancel claim 50. Added material is shown in underlined type, and deleted material is shown in ~~strikeout~~ type or within [[double brackets]]:

Listing of Claims

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently Amended) A sample collection device for assay comprising:

a handle portion having a first end and a second end;

a collector portion having a first end ~~operably connected to~~ and a second end,

the collector portion first end detachably coupled to the handle portion second end and

the collector portion second end having

a base being movable relative to the handle portion second end when the collector portion first end is coupled to the handle portion second end, ~~the collector portion having at least an extended size and a contracted size, the sizes being defined by a configurable distance between the collector portion second end and the handle portion second end;~~

a plunger arm coupled to the base and including a first diameter portion and a second diameter portion, the first diameter portion being smaller than the second diameter portion; and

an expandable sponge disposed on the ~~collector portion~~ first diameter portion and on the second diameter portion of the plunger arm between an end wall of the collector portion and the base resulting in an extended collection size of the sponge; and ~~and having a dry size, a first collection size when the sponge holds a first amount of sample and a second collection size when the sponge holds a second amount of sample, the first collection size being less than the second collection size;~~

wherein the plunger arm is moved relative to the handle portion second end such that the second diameter portion of the plunger arm engages a flange reconfiguring the sponge to a smaller sample retaining size and discharging a first portion of the sample for assay and retaining a second portion of the sample in the sponge for subsequent assay.

~~wherein a sufficient sample is collected for assay when the sponge second collection size is substantially equal to the collector portion extended size;~~

~~wherein the sponge is disposed between the base and the handle portion second end, and when the collector portion second end is moved relative to the handle portion second end to reconfigure the collector portion from the extended size to the contracted size, a sample portion sufficient for assay is discharged from the sponge through the base; and~~

~~wherein the collector portion includes a blocking portion configured to engage the handle portion second end to define a sample retaining size of the collector portion and impede movement of the collector portion second end relative to the handle portion second end, such that movement of said collector portion second end to engage said blocking portion with said handle portion second end allows the discharge of a first portion of sample for assay from said sponge while placing the sponge in the first collection size and retaining a second portion of sample in said sponge for subsequent assay.~~

2.-3. (Canceled)

4. (Previously Presented) The sample collection device for assay of claim 1, wherein the sponge is made from a fluid absorbing material and the sample is discharged from the sponge by compressing the sponge between the base and the handle portion second end.

5. (Canceled)

6. (Currently Amended) The sample collection device for assay of claim 1, wherein the collector portion includes an elongate member~~, the blocking~~ and a locking portion that includes a raised portion formed on the elongate member, and the handle portion second end includes a wall sized to engage with the raised portion of the elongate member when the

collector portion is moved from one of the extended size ~~and the contracted size~~ to the sample retaining size.

7. (Currently Amended) The sample collection device for assay of claim 1, wherein the handle portion includes a housing defining an opening for slidably receiving the collector portion so as to permit the collector portion to be selectively configurable between the extended size and the ~~contracted~~ sample retaining size.

8.-11. (Canceled)

12. (Currently Amended) The sample collector device for assay of claim 1, wherein the sponge has a first length when the sponge has the ~~first collection~~ sample retaining size, the sponge has a second length when the sponge has the ~~second~~ extended collection size, and the collector portion has an extended length when the ~~collector portion has the extended size,~~ sponge is disposed on the plunger arm between the end wall of the collector portion and the base; and

wherein a sufficient sample is collected for assay when the sponge ~~second length~~ extended collection size is substantially equal to the collector portion extended length.

13. (Currently Amended) The sample collector device for assay of claim 1, wherein the sponge size is reduced from the ~~second~~ extended collection size to the ~~first collection~~ sample retaining size when the collector portion is configured from [[the]] an extended size to ~~the contracted~~ a sample retaining size.

14. (Currently Amended) A test device in combination with the sample collection device for assay of claim 1, the test device being adapted to connect with the sample collection device and including a tester to assay for analytes in the sample, the test device including:

an opening sized to receive the handle portion; and

a discharge surface adapted to engage with the collector portion, wherein the sponge ~~second~~ extended collection size is substantially equal to the collector portion extended collection size before engaging the collector portion with the discharge surface, and the sample collection device is in fluid communication with the tester and the collector portion is configured in the ~~contracted~~ sample retaining size when the collector portion is engaged with the discharge surface.

15. (Previously Presented) The test device in combination with the sample collection device for assay of claim 14, wherein the handle portion second end includes an engagement surface and the test device includes a mating surface adapted to engage with the engagement surface, wherein the handle portion is fixed to the test device when the engagement surface engages with the mating surface.

16. (Previously Presented) The test device in combination with the sample collection device for assay of claim 15, wherein the mating surface engages with the engagement surface by elastic deformation of at least one of the mating surface and the engagement surface.

17. (Previously Presented) The test device in combination with the sample collection device for assay of claim 15, wherein the handle portion is fixed to the test device by a friction fit between the engagement and mating surfaces.

18. (Currently Amended) The test device in combination with the sample collection device for assay of claim 15, wherein the sponge ~~second~~ extended collection size is substantially equal to the collector portion extended collection size when the mating surface engages with the engagement surface.

19. (Previously Presented) The test device in combination with the sample collection device for assay of claim 15, wherein the handle portion includes a second engagement surface and the test device includes a second mating surface adapted to engage

with the second engagement surface, wherein when the second engagement surface is in contact with the second mating surface, the discharge surface engages with the collector portion.

20. (Currently Amended) The test device in combination with the sample collection device for assay of claim 14, wherein the tester is a lateral flowstrip in fluid communication with the sponge when the handle portion is fixed to the test device and the collector portion is in the ~~contracted~~ sample retaining size.

21. (Currently Amended) The test device in combination with the sample collection device for assay of claim 14, wherein the test device further includes an ampoule containing fluid and the ampoule is violated when the ~~sponge~~ collector portion is ~~equal~~ configured to the ~~first collection~~ sample retaining size.

22. (Previously Presented) The test device in combination with the sample collection device for assay of claim 14, wherein the handle portion first end comprises a grip and the first end is removable from the second end.

23. (Currently Amended) The sample collection device for assay of claim 1, wherein the second ~~amount~~ portion of sample corresponds to an assay sample that is substantially contained in the sponge, the assay sample being transferable from the sponge to a test device for assay of the assay sample.

24. (Canceled)

25. (Currently Amended) The test device in combination with the sample collection device for assay of claim 14, wherein the sponge has the ~~first collection~~ sample retaining size when the sample collector is in fluid communication with the tester.

26.-45. (Canceled)

46. (Currently Amended) A sample collection device for assay comprising:

a handle portion having a first end and a second end;

a collector portion having a first end ~~operably connected to~~ and a second end,

the collector portion first end being coupled to the handle portion second end and

the collector portion second end being movable relative to the handle portion second end when the collector portion first end is coupled to the handle portion second end, the collector portion having at least an extended size and a sample retaining size, the sample retaining size being smaller than the extended size, the sizes being defined by a configurable distance between the collector portion second end and the handle portion second end;

the collector portion second end also including a plunger arm coupled to the collector portion and including a first diameter portion and a second diameter portion, the first diameter portion being smaller than the second diameter portion; and

a ~~blocking~~ locking portion disposed on the collector portion, the ~~blocking~~ locking portion being spaced from the handle portion second end when the collector portion is configured in the extended size and the ~~blocking~~ locking portion being engaged with the handle portion second end when the collector portion is configured in the sample retaining size, and

a sponge disposed on the ~~collector portion~~ first diameter portion and the second diameter portion of the plunger arm between the locking portion and the collector portion second end resulting in an extended collection size of the sponge ~~and having dry size, a first collection size~~ when the sponge holds a first amount of sample ~~and a second collection size when the sponge holds a second amount of sample~~;

wherein the plunger arm is moved relative to the handle portion second end such that the second diameter portion of the plunger arm engages the locking portion reconfiguring the sponge to a smaller sample retaining size and discharging a first portion of the sample for assay and retaining a second portion of sample in the sponge for subsequent assay.

~~wherein the sponge has the second collection size when the blocking member is spaced from the handle portion second end and the sponge has the first collection size when the blocking member is engaged with the handle portion second end,~~

~~wherein the second amount of sample is sufficient for a first assay of sample and the first amount of sample is sufficient for a second assay of the sample subsequent to the first assay~~.

47. (Currently Amended) The sample collection device for assay of claim 46, wherein the ~~blocking~~ locking portion is formed on the collector portion.

48. (Currently Amended) The sample collection device for assay of claim 47, wherein the ~~collector~~ locking portion ~~includes a first part including the blocking portion and a second part that is smaller than the first part and wherein the second part~~ is received within the handle portion when the collector portion is configured from the extended size to the sample retaining size.

49. (Currently Amended) The sample collection device for assay of claim 46, wherein the collector portion further ~~comprising~~ includes:

a first ~~elongate~~ diameter portion having a first length and a first width dimension wherein the first length substantially corresponds to the sample retaining size of the sponge, and

a second ~~elongate~~ diameter portion having a second length and a second width dimension, wherein the total length of the first length and the second length substantially corresponds to the extended collection size of the sponge

~~wherein the handle portion second end defines an opening sized for slidably receiving the collector portion, the opening defining a width dimension that is smaller than the first width dimension and greater than the second width dimension~~.

50. (Canceled)

51. (Currently Amended) The sample collection device for assay of claim 46, wherein when the ~~sponge~~ collection portion has the ~~first collection~~ extended size and ~~the retaining portion~~ is configured from the extended size to the sample retaining size, the sponge is configured from the ~~second~~ extended collection size to the ~~first collection~~ sample retaining size and a sample sufficient ~~for the~~ for a first assay is expressed from the sponge.

52. (Previously Presented) The sample collection device for assay of claim 46, wherein the sponge is made from a fluid absorbing material and the collector portion expresses fluid sufficient for assay of sample from the sponge when the collector portion is configured from the extended size to the sample retaining size.

53.-72. (Canceled)

73. (Currently Amended) A sample collection device for assay comprising:

a handle portion having a first end and a second end;

a collector portion having a first end operably connected to a second end,

the collector portion first end being coupled to the handle portion second end and

the collector portion second end having

a base ~~and~~ being movable relative to the handle portion second end when the collector portion first end is coupled to the handle portion second end, ~~the collector portion having at least an extended size and a contracted size, the extended and contracted sizes being defined by a configurable distance between the collector portion second end and the handle portion second end;~~

the collector portion second end also including a plunger arm coupled to the collector portion and including a first diameter portion and a second diameter portion; and

a sponge disposed on the ~~collector portion~~ first diameter portion and on the second diameter portion of the plunger arm between the handle portion second end and the base resulting in an extended collection size of the sponge; and ~~having a dry size, a first collection~~

~~size when the sponge holds a first amount of the sample and a second collection size when the sponge holds a second amount of the sample, the first collection size being less than the second collection size and the first amount of sample being sufficient for assay;~~

wherein the base is moved relative to the handle portion second end such that the second diameter portion of the plunger arm engages a flange reconfiguring the sponge to a smaller sample retaining size and discharging a first portion of the sample for assay and retaining a second portion of the sample in the sponge for subsequent assay.

~~wherein a sufficient sample is collected for assay when the sponge second collection size is substantially equal to the collector portion extended size, and~~

~~wherein, the sponge is disposed between the base and the handle portion second end, and when the base is moved relative to the handle portion second end to reconfigure the collector portion from the extended size to the contracted size, a portion of the sample in the sponge suitable for assay is discharged from the sponge and the sponge is placed in the first collection size and holds the first amount of sample~~.

74. (Currently Amended) The sample collection device for assay of claim ~~75~~ 73, wherein the second ~~amount~~ portion of sample includes at least a first assay sample and a second assay sample.

75. (Previously Presented) The sample collection device for assay of claim 73, wherein the sponge is made from a fluid absorbing material and the sample is discharged from the sponge by compressing the sponge between the base and the handle portion second end.

76. (Canceled)

77. (Currently Amended) A sample collection device for assay comprising:

a handle portion having a first end and a second end;

a collector portion coupled to the handle portion second end and selectively configurable between at least an extended size and a ~~contracted~~ sample retaining size;

the collector portion also including a movable base positioned at a first length from the handle portion second end when the collector portion is in the extended size and positioned at a second length from the handle portion second end when the collector portion is in the sample retaining size,

the collector portion also including a plunger arm coupled to the base and including a first diameter portion and a second diameter portion; and

an expandable sponge disposed on the ~~collector portion~~ first diameter portion and on the second diameter portion of the plunger arm between the collector portion and the handle portion second end and having a dry size, a ~~first collection~~ sample retaining size when the sponge holds a first amount of the sample and a ~~second collection~~ extended size when the sponge holds a second amount of the sample, the ~~first collection~~ sample retaining size being ~~less~~ smaller than the ~~second collection~~ extended size and the first amount of sample being sufficient for assay;

wherein a sufficient sample is collected for assay when the sponge ~~second collection~~ extended size is substantially equal to the collector portion extended size, ~~wherein the collector portion includes a base spaced at a first length from the handle portion second end when the collector portion is in the expanded size and the base is spaced at a second length from the handle portion second end when the collector portion is in the contracted size,~~

wherein the ~~collector portion~~ plunger arm is an elongate member having a proximal end adjacent the handle portion second end and the base formed at a distal end, wherein the base is a perforated disc,

wherein the sponge is made from a fluid absorbing material that is movable along the elongate member to place the sponge in the ~~second~~ extended collection size and

wherein the ~~elongate member~~ plunger arm has a first ~~elongate~~ diameter portion having a first length and a first width dimension wherein the first length substantially corresponds to [[a]] the sample retaining size of the sponge, a second ~~elongate~~ diameter portion proximal from the handle portion second end relative to the first ~~elongate~~ diameter portion and having a second length and a second width dimension that is smaller than the first width dimension, wherein the total length of the first length and the second length substantially corresponds to the extended collection size of the sponge, and wherein the handle portion second end defines

an opening sized for slidably receiving the ~~elongate member~~ plunger arm, ~~the opening defining a width dimension that is smaller than the first width and greater than the second width,~~ such that as the ~~elongate member~~ plunger arm slides within the opening, the ~~first width~~ opening impedes the movement of the first length of the ~~elongate member~~ plunger arm, thus defining the sample retaining size.

78. (Canceled)

REMARKS

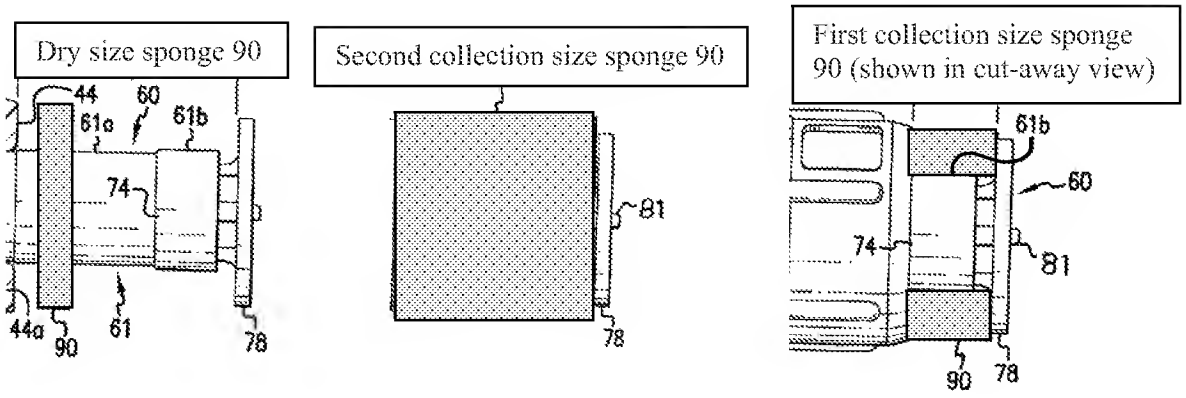
The Office Action sent on November 30, 2009, was received and its contents carefully reviewed. Claims 1, 4, 6, 7, 12-23, 25, 46-52, 73-75, and 77 were originally pending prior to the Office Action of November 30, 2009. Above, Applicants amended claims 1, 6, 7, 12-14, 18, 20, 21, 23, 25, 46-49, 51, 73, 74, and 77 as shown in the listing of claims. Applicants canceled claim 50. Applicants amended the claims to provide additional structural and component descriptions for the features of the claimed invention. Applicants also amended the claims to recite further structural pieces and components of the claimed invention as opposed to characteristics of components or relative references to other structures in the claimed invention. There is ample support for the above amendments in the original disclosure, for example in at least paragraphs [0034-0046], in Figures 1-5, and throughout the original disclosure. Applicants respectfully submit that no new material was added. Claims 1, 4, 6, 7, 12-23, 25, 46-49, 51, 52, 73-75, and 77 remain pending and are believed to be in condition for allowance. Applicants respectfully request reconsideration of this application in light of the following remarks.

A. Claim Rejections under 35 U.S.C. § 102

Claims 1, 4, 6-7, 9, 12-23, 25, 46-52, and 73-76 stand rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Shah U.S. Patent No. 4,014,322 ("the Shah patent"). In view of the comments below, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

1. The Shah Patent does not Disclose or Suggest all Features of Independent Claim 1

The present invention is generally directed to a sample collector and a test device. The sample collector and test device can be used to collect and assay fluid samples to detect the presence of analytes in a collected fluid sample. Claim 1 recites a sample collector and test device that employs an expandable sponge with a dry size before a sample is collected, a second collection size after a sample has been collected, and a first collection size that results from expressing a portion of the sample from the sponge when the sponge was its second collection size. Graphically, the sizes may be depicted as follows:



As shown in the listing of claims, independent claim 1 recites the sample collection device for assay that includes a handle portion, a collector portion, and the expandable sponge. The handle portion and collection portion are used with a housing to effect the sponge sizing.

Claim 1 further recites the handle portion has a first end and a second end, and the collector portion has a first end and a second end. Additionally, claim 1 recites that the first end of the collector portion is operably connected to the second end. The first end of the collector portion is detachably coupled to the second end of the handle portion. The second end of the collector portion has a base and is movable relative to the second end of the handle portion when the first end of the collector portion is coupled to the second end of the handle portion. The collector portion has at least an extended size and a contracted size, and the sizes are defined by a configurable distance between the second end of the collector portion and the second end of the handle portion.

Claim 1 recites that the expandable sponge is disposed on the collector portion and has a dry size, a first collection size, and a second collection size as shown above. The first collection size is when the sponge holds a first amount of sample, and the second collection size is when the sponge holds a second amount of sample. As shown above, the first collection size is smaller than the second collection size. A sufficient sample has been collected when the second collection size is substantially equal to the extended size of the collector portion. Further, claim 1 recites that the sponge is disposed between the base and the second end of the handle portion. When the second end of the collector portion is moved

relative to the second end of the handle portion, the collector portion is reconfigured from the extended (second) size to the contracted (first) size, and a sample portion sufficient for assay is discharged from the sponge through the base.

Additionally, claim 1 recites that the collector portion includes a blocking portion configured to engage the second end of the handle portion to define a sample retaining size of the collector portion and to impede movement of the second end of the collector portion relative to the second end of the handle portion, such that movement of the second end of the collector portion to engage the blocking portion with the second end of the handle portion allows the discharge of a first portion of sample for assay from the sponge while placing the sponge in the first collection size and retaining a second portion of sample in the sponge for subsequent assay.

The Shah patent describes a specimen collecting device with a container and a liquid sampling means. The liquid sampling means include compressible liquid absorption means for receiving the liquid specimen and handle means for supporting the absorption means. The device also has means for compressing the absorption means in the container. See col. 1, lines 43-50 of the Shah patent. While the Shah patent discloses that the compressing means releases the specimen from the absorption means into the container chamber, there is no disclosure or suggestion of retaining a second portion of sample in the sponge for subsequent assay as recited in independent claim 1 of the present application. See col. 2, lines 3-5 of the Shah patent.

For example, the Shah patent discloses a sponge 56, but there is no disclosure or suggestion in the Shah patent that the sponge has a dry size, a first collection size, and a second collection size, where sufficient sample is collected when the sponge is in the first collection size and that a second portion of sample in the sponge is retained for subsequent assay when the sponge is compressed to the second collection size as recited in claim 1 of the present application. Also, there is no disclosure or suggestion in the Shah patent of a blocking portion of the collector configured to engage the second end of the handle portion to define a sample retaining size such that movement of the collector portion to the blocking position allows the discharge of a first portion of sample for assay while retaining a second portion of sample in the sponge for subsequent assay.

In the Office Action of November 30, 2009, the Examiner asserted that Figures 1 and 2 of the Shah patent show a sponge 56 with a dry size and that Figures 3-5 disclose sponge 56 engaged between plate 50 and lid 34 to express only a portion of the sample from the sponge 56. However, this is not evident from the Shah patent, and even if it were, there is no disclosure or suggestion that sufficient sample is collected when the sponge is in the first collection size and that a second portion of sample in the sponge is retained for subsequent assay when the sponge is compressed to the second collection size as recited in claim 1 of the present application. Figures 1 and 2 of the Shah patent illustrate the sponge 56 with a dry size when exposed for collecting the specimen. See also col. 3, lines 48-51. As the sponge 56 absorbs a sample, it expands laterally and longitudinally relative to the shaft 40. See col. 3, lines 65-68 and Figure 3.

Figure 4 of the Shah patent illustrates the specimen being released from the sponge. See also col. 4, lines 18-42. The Shah patent describes the manner in which the shaft is moved outwardly through the lid aperture 38 to reduce the spacing between the plate and lid to compress the wetted sponge. The Shah patent further describes that the movement of the shaft stops at an outer position when the specimen has been substantially compressed from the sponge. See col. 4, lines 28-30. The Shah patent describes a dry sponge 56, collecting a sample specimen by wetting the sponge 56 with the specimen, and expressing the specimen into the container chamber 28 by raising the wetted sponge 56 and compressing the sponge 56 between the plate 50 and the lid 34 to release the sample.

There is no mention or suggestion in the Shah patent of the sponge having two collection sizes much less holding sufficient sample for subsequent assay when the sponge is a smaller (first) collection size. See at least page 2, paragraph 2 of the Office Action sent November 30, 2009. In previously making the rejections based on the Shah reference, the Examiner asserted that the Shah patent teaches that "[a]bsorbent/sponge (56) has a first size prior to sample application where it is the width of slot (52) and a second larger size when the sample is applied that is larger than the distance between slot (52) and slot (54)." See page 2 of the Office Action sent October 2, 2007. As outlined above, the sponge described in the Shah reference has a dry size and a wet size. The sponge described in the Shah reference does

not, however, have a first collection size and a second collection size as recited by claim 1 of the present application.

On page 3 of the Office Action sent February 9, 2009, the Examiner asserted that "Shah teaches in column 4, lines 30-34 [that] slot (52) retains the sponge(56) in a compressed configuration and this compressed configuration is what the Office intended by a 'first size(52).'" Yet in this configuration, the handle 48 in the Shah patent is broken away from the remainder of the shaft 40 at the second slot 54 to permit compact storage of the chamber and sample until the lid is removed and the sample is analyzed. See col. 4, lines 36-42. There is no disclosure or suggestion in the Shah patent of the sponge holding sufficient sample for assay when the sponge is a smaller (first) collection size. In fact, the Shah patent discloses that the sample on the bottom of the container will be poured from the container for analysis. See col. 4, lines 40-42. The Shah reference does not disclose or suggest that the sponge 56 has another collection size other than the one depicted and discussed with reference to FIG. 3 that holds an amount of sample for assay.

As such, the Shah patent fails to disclose or suggest all the features recited in independent claim 1 of the present application. Accordingly, Applicants respectfully submit that claim 1 is allowable over the Shah patent. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b).

2. The Shah Patent Does Not Disclose or Suggest All the Features of Independent Claims 46, 73, and 77.

Independent claims 46, 73, and 77 recite similar features as those recited in independent claim 1. For example, each of independent claims 46, 73, and 77 recite a "sponge disposed on the collector portion and having a dry size, a first collection size when the sponge holds a first amount of sample and a second collection size when the sponge holds a second amount of sample." Independent claim 46 further recites that "the second amount of sample is sufficient for a first assay of sample, and the first amount of sample is sufficient for a second assay of the sample subsequent to the first assay." Independent claims 73 and 77 each additionally recite "the first amount of sample being sufficient for assay" and "a

sufficient sample is collected for assay when the sponge second collection size is substantially equal to the collector portion extended size."

As outlined above, independent claim 1 recites a "collector portion first end detachably coupled to the handle portion second end and the collector portion second end . . . being movable relative to the handle portion second end when the collector portion is coupled to the handle portion." Independent claims 46 and 73 each recite "a collector portion first end being coupled to a handle portion second end and the collector portion second end" "being movable relative to the handle portion second end when the collector portion first end is coupled to the handle portion second end." Independent claim 77 recites that "the collector portion is an elongate member" and that "the handle portion second end defines an opening sized for slidably receiving the elongated member."

As discussed previously in the Examiner's interview, in the previous Office Actions, the Examiner equated outer portion 48 of shaft 40 of the Shah reference with Applicants' claimed "handle portion." As further discussed during the interview, with reference in particular to FIG. 3, the Shah reference does not disclose or otherwise suggest that any part of either shaft 40 or the plate 50 is movable relative to the outer portion 48 when the end of shaft 40 at slot 54 is coupled to the outer portion 48. The Shah reference also fails to disclose or otherwise suggest that outer portion 48 or any other portion of shaft 40 defines an opening sized for slidably receiving an elongated member. Instead, the Shah reference discloses the outer portion 48 and the remainder of shaft 40 and plate 50 are fixed relative to each other (see in particular FIG. 3) when the outer portion 48 is coupled with the remainder of shaft 40. For at least these additional reasons, independent claims 1, 46, 73, and 77 are patentably distinguishable from the Shah reference.

Each of independent claims 1, 46, 73, and 77 recites a sponge with a dry size and first and second collection sizes, wherein each of the first and second collection sizes holds respective amounts of sample sufficient for assay. As outlined above with regard to claim 1, the Shah patent fails to disclose or suggest these features recited in the independent claims of the present application.

Accordingly, Applicants respectfully submit that claims 46, 73, and 77 are allowable over the Shah patent for at least the reasons outlined above with regard to claim 1. Applicants

respectfully request reconsideration and withdrawal of the rejection of claims 46, 73, and 77 under 35 U.S.C. § 102(b).

3. The Shah Patent Does Not Disclose or Suggest All the Features of Dependent Claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76.

Claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76 each ultimately depend upon independent claims 1, 46, and 73, respectively, and thereby include all the limitations of the independent claims while reciting additional features of the present invention. Applicants respectfully traverse the rejection of claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76 for similar reasons as outlined above with regard to the rejection of claims 1, 46, and 73 under 35 U.S.C. § 102(b). As discussed above, the Shah patent fails to disclose all the elements and limitations recited in independent claims 1, 46, and 73 of the present application. As such, the Shah patent also fails to disclose all the features and limitations of dependent claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76 as well. Accordingly, Applicants respectfully submit that claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76 are allowable over the Shah patent, as outlined above. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76 under 35 U.S.C. § 102(b).

B. Claim Rejections under 35 U.S.C. § 103

Claim 77 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Shah U.S. Patent No. 4,014,322 ("the Shah patent"). In view of the comments below, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

1. The Shah Patent does not Disclose or Suggest all Features of Independent Claim 77

Independent claim 77 recites similar features as those recited in independent claims 1, 46, and 73. For example, each of independent claims 46, 73, and 77 recites a "sponge disposed on the collector portion and having a dry size, a first collection size when the sponge holds a first amount of sample and a second collection size when the sponge holds a second amount of sample." Independent claim 77 additionally recites "the first amount of sample

being sufficient for assay" and "a sufficient sample is collected for assay when the sponge second collection size is substantially equal to the collector portion extended size."

Independent claim 77 recites a sponge with a dry size and first and second collection sizes, wherein each of the first and second collection sizes holds respective amounts of sample sufficient for assay. As outlined above with regard to claims 1, 46, and 73, the Shah patent fails to disclose or suggest these features recited in the independent claims of the present application.

Accordingly, Applicants respectfully submit that claim 77 is allowable over the Shah patent for at least the reasons outlined above with regard to claims 1, 46, and 73. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 77 under 35 U.S.C. § 103(a).

C. Conclusion

In view of the above amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.
If the Examiner finds that any issue remains unresolved, or if any new issue arises that could be resolved through discussions with Applicants' representative, Applicants invite the Examiner to telephone the undersigned to expedite further prosecution of this application.

Respectfully submitted,

J.A. LINDEMAN & CO. PLLC

/Joseph A. Parisi, Reg. No. 53,435/
Joseph A. Parisi
Registration No. 53,435

Customer Number: 92049

J.A. LINDEMAN & CO. PLLC
3190 Fairview Park Drive, Suite 480
Falls Church, VA 22042
703-776-9700 – Telephone
703-776-9701 – Facsimile